

IFW

00005.001300

PATENT APPLICATION



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

YUJI UENO, ET AL.

Application No.: 10/587,848

Filed: July 28, 2006

For: PYRAZOLOACRYDONE  
DERIVATIVE-CONTAINING  
SOLUTION

)  
:  
) Examiner: Not Yet Assigned  
:  
) Group Art Unit: Not Yet Assigned  
:  
)  
:  
)  
:  
)  
:  
)  
:  
) December 11, 2006

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SUBMISSION OF MISCELLANEOUS PCT FORMS

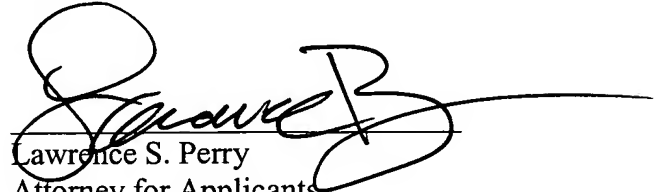
Sir:

Enclosed to complete the record and for the Examiner's convenience is Form PCT/IB/338, an English translation of the International Preliminary Report on Patentability (Form PCT/IB/373) and the Written Opinion of the International Searching Authority (Form PCT/ISA/237) in the above-identified application. The references discussed in the Written Opinion (or their patent family member equivalents) were all cited in Applicants' September 27, 2006 Information Disclosure Statement.

Entry hereof is earnestly solicited.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



Lawrence S. Perry  
Attorney for Applicants  
Registration No. 31,865

FITZPATRICK, CELLA, HARPER & SCINTO  
30 Rockefeller Plaza  
New York, New York 10112-3801  
Facsimile: (212) 218-2200

LSP\ac

NY\_Main 604815\_1

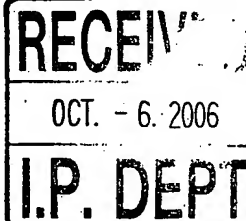
From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis.3(c) and 72.2)

To:

KYOWA HAKKO KOGYO CO., LTD.  
6-1, Ohtemachi 1-chome  
Chiyoda-ku, Tokyo 1008185  
JAPON



Date of mailing (day/month/year)

28 September 2006 (28.09.2006)

Applicant's or agent's file reference  
1651**IMPORTANT NOTIFICATION**International application No.  
PCT/JP2005/002088International filing date (day/month/year)  
04 February 2005 (04.02.2005)

Applicant

KYOWA HAKKO KOGYO CO., LTD. et al

**1. Transmittal of the translation to the applicant.**

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

**2. Transmittal of the copy of the translation to the designated or elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

**3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer

Masashi Honda

Facsimile No. +41 22 338 82 70

Facsimile No. +41 22 338 82 70

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 1651	<b>FOR FURTHER ACTION</b>	See item 4 below
International application No. PCT/JP2005/002088	International filing date ( <i>day/month/year</i> ) 04 February 2005 (04.02.2005)	Priority date ( <i>day/month/year</i> ) 06 February 2004 (06.02.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant KYOWA HAKKO KOGYO CO., LTD.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- |                                     |              |   |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the report   |
| <input type="checkbox"/>            | Box No. II   | Priority  |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention  |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited   |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application  |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application   |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Genève 20, Switzerland  Facsimile No. +41 22 338 82 70	Date of issuance of this report 19 September 2006 (19.09.2006)  Authorized officer  <div style="text-align: center; font-weight: bold; font-size: 1.2em;">Masashi Honda</div>  e-mail: pt08@wipo.int
---	---

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/002088

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	3, 4	YES
	Claims	1, 2, 5-7	NO
Inventive step (IS)	Claims		YES
	Claims	1-7	NO
Industrial applicability (IA)	Claims	1-7	YES
	Claims		NO

2. Citations and explanations:

Document 1: WO 2000/021962 A1 (KYOWA HAKKO KOGYO CO., LTD.) 20 April 2000

Document 2: Shun'ichi NAITO, "Yakuzai no Antei-sei," 3<sup>rd</sup> edition, 1<sup>st</sup> print, Kabushiki Kaisha Hirokawa Shoten, 01 April 1976

Document 3: Mitsuo MATSUMOTO et al., "Yakuzaigaku Manual," 1<sup>st</sup> edition, Nanzando Co., Ltd., 20 March 1989

Document 4: Translated and edited by the Pharmaceutical society of Japan, "Iyaku Tenkabutsu Handbook," Maruzen Co., Ltd., 30 March 1988

<Claims 1, 2, and 5-7>

The inventions of claims 1, 2, and 5-7 do not appear to possess novelty based on document 1 cited in the ISR.

Document 1 describes a stabilization method for an aqueous solution containing a pyrazoloacridone derivative or a pharmacologically acceptable salt thereof characterized by, based on background technology wherein a pyrazoloacridone derivative easily undergoes oxidative decomposition in aqueous solution, adding acid to a solution that contains a pyrazoloacridone derivative represented by general formula (I) or a pharmacologically acceptable salt thereof, substituting air of a sealed chamber containing said solution with inert gas, and sealing said chamber, and further describes that pH of said aqueous solution is 1-7.

<Claims 3 and 4>

The inventions of claims 3 and 4 do not appear to involve an inventive step based on documents 1-4 cited in the ISR.

As described documents 2-4, the use of edetic acid or a salt thereof as an antioxidant is generally known.

Also, the selection decision of the type and amounts in combination of additives used appropriate for objectives is commonly performed by persons skilled in the art in the field of pharmaceutical products, and specifying the type of additives used in the aqueous solution described in claim 1 and confirming a stabilization results of said aqueous solution to make the inventions of claims 3 and 4 could be easily conceived of by a person skilled in the art.

# PATENT COOPERATION TREATY

TRANSLATION

From the  
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing  
(day/month/year)

Applicant's or agent's file reference

**1651**

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

**PCT/JP2005/002088**

International filing date (day/month/year)

**04.02.2005**

Priority date (day/month/year)

**06.02.2004**

International Patent Classification (IPC) or both national classification and IPC

Applicant

**KYOWA HAKKO KOGYO CO., LTD.**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/002088

Box No. 1

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
☐ This opinion has been established on the basis of a translation from the original language into the following language  
\_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material  
☐ in written format  
☐ in computer readable form
  - c. time of filing/furnishing  
☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments: